

# Public consultation on ACT EU multi-stakeholder platform (ACT EU MSP) participation and priorities for discussion

Fields marked with \* are mandatory.



## Background information

The [Accelerating Clinical Trials in the EU \(ACT EU\)](#) is an EC-HMA-EMA initiative that was launched on 13 January 2022 with the aim of further developing the EU as a competitive centre for innovative clinical research. This objective was also reflected in the [Clinical Trials Regulation](#), which aims to establish high standards of public transparency and safety for clinical trials participants.

The success of clinical trials relies on a multitude of stakeholders and therefore regular dialogue between all parties involved can help to identify key advances in clinical trial methods, technology and science or roadblocks, and by finding practical solutions to enable and drive change. ACT EU outlines a set of 10 priority actions ([ACT EU 2022-2026 workplan](#)), with a key action being the establishment of a multi-stakeholder platform (MSP).

The ACT EU MSP is expected to be the main forum where stakeholders can discuss all aspects related to clinical trials and develop a better understanding of each other's perspectives. The platform is intended to meet regularly and discuss topics according to an established workplan. It is foreseen that the MSP will be supported by ad hoc topic groups responsible for more technical discussions. The "[ACT EU multi-stakeholder platform concept paper](#)" outlines the key objectives and governance aspects of the MSP. It is anticipated that the ACT EU MSP kick-off meeting will take place at the beginning of Q2 2023.

In order to initiate the setting up of the platform and its workplan, a public stakeholder consultation is hereby launched. We would appreciate your feedback and interest in being part of the ACT EU MSP and on the topics you consider high priority for discussion in 2023-2024.

The completion of this survey is expected to take 10-15 minutes and will be available until the 3rd of March 2023 (midnight CET).

In case of queries please contact: [ACTEU@ema.europa.eu](mailto:ACTEU@ema.europa.eu).

We take this opportunity to thank you in advance for your contribution!

## Data protection statement for 'Public consultation on ACT EU multi-stakeholder platform (ACT EU MSP) participation and priorities for discussion'.

By participating in this survey, your submission will be assessed by EMA. However, with exception of question 4, EMA does not collect, process or store your personal data. Therefore, please make sure that you do not reveal your identity or include other personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format. If in response to question 4 you provide your personal details, you would need to confirm that you have read and understood the data protection statement enclosed below.

### Survey

#### 1. Affiliation

- Academics as users of clinical trial data
- Clinical Research Organisations (CRO) and other clinical trial service providers, including consultants
- Clinical trial investigators
- Ethicists and ethics committee members
- Healthcare professionals (HCP) and HCP organisations
- Health technology assessment (HTA) bodies
- Inspectorates
- Patients and patient organisations
- Payers
- Policy makers
- Regulators: medicines approval regulators, clinical trial assessors, safety (Pharmacovigilance in clinical trials) assessors, clinical development advisors, and medical device bodies
- Research funders
- Sponsors, incorporating academia and pharmaceutical companies, notably small and medium-sized enterprises (SMEs)
- Other

1.1 If "Other" was selected, please specify:

industry association

2. In order to deliver its objectives, ACT EU has a series of priority actions. Please select the top 3 topics based on ACT EU priority actions that you deem the MSP should focus on initially. For each of the priority action selected, additional details can be added.

*between 1 and 3 choices*

- 1. The successful and timely implementation of the Clinical Trials Regulation (CTR) and its implementing acts.
- 2. Good Clinical Practices (GCP) modernisation informed by the revision of ICH guidance.
- 3. The analysis of clinical trial data to support policymaking, funding on research outputs, and to support evidence-based decision making.

- 4. Need for methodologies guidance such as on Machine Learning/Artificial Intelligence impacted CTs, decentralised CTs and In Vitro Diagnostics Regulation/CTR interface (to strengthen links between innovation and scientific advice fora).
- 5. Clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs (serving as an educational "ecosystem").
- 6. Regulatory support structures for evidence generation and enabling innovation.

Additional comments on topic 1

*500 character(s) maximum*

Additional comments on topic 2

*500 character(s) maximum*

Additional comments on topic 4

*500 character(s) maximum*

2.1 Taking into consideration the ACT EU and MSP objectives, list any additional priority topic not included in the above selection.

*1000 character(s) maximum*

The structured questionnaire only permits the selection of three choices, which is not practical. For commercial research all items – except perhaps Option 5 – are important ACRO would like to select a fourth option as an additional priority for ACT EU, which is Option #6 (“regulatory support structures for evidence generation and enabling innovation”). Moreover, some key elements which could accelerate clinical trials are actually OMITTED from this list – for example, lessons learnt from accelerated COVID trials (rolling review, increased Regulatory engagement). We encourage flexibility and openness for ACT EU to be able to consider all activities which could support the acceleration of clinical trials in the EU.

3. The ACT EU multi-stakeholder platform concept paper outlines the scope, objectives and organisation of the MSP. Please provide any comments you may have on the proposal.

*2000 character(s) maximum*

ACRO is pleased to see the need for an innovative approach to regulation listed as a key objective of the MSP.

We would like to focus on three aspects of the complex matrix of regulations that impact clinical trials in the EU.

First, we believe there is need to facilitate increased coordination and cross-linkage between clinical trial regulation and multi-sector data protection regulations such as GDPR. As the volume of data and variety of data sources increase under innovative trial designs such as decentralised trials, we believe it is important for the MSP to include data protection regulation (and the role of the clinical trial participant as both research subject and data subject).

Second, there needs to be increased coordination and cross-linkage across the various healthcare-specific regulations and also across EMA initiatives. At the regulatory level, the MDCG guidance on the interface between the Clinical Trial Regulation and the IVDR Regulation was valuable to industry. Future cross-linking guidances such as this will be important. At the Agency level, attention to the interdependence of various EMA initiatives focused on clinical trials (and cross-initiative coordination) is vital. For example, the success of ACT EU depends, in large part, on the success of the CTIS.

Finally, the MSP needs to examine the potential for greater regulatory harmonization across the 27 member states where it is possible and appropriate. And, in those cases where this is not practicable or feasible, it would be helpful to, instead, promote greater transparency of regulatory variability at the national level (as seen in the Appendix to the EU DCT Recommendations Paper). In addition, increased harmonization in regulations of advanced therapies is important. Lastly, greater harmonization of regulations between EU and non-EU regulators (e.g., ICH observant Regulators such as FDA, HC, MHRA, PMDA) is vital. We note the proposals from Project Orbis.

#### 4. Would your organisation be interested in joining the MSP?

- Yes (By clicking here you demonstrate your consent to process personal data as explained in the data protection statement which you can read by clicking here. If you do not wish to consent and provide this data, simply click 'no' as an answer for this question.)
- No

#### \* 4.1. Please provide your contact details (i.e. Name, affiliation and email address)

Karen Noonan  
Senior Vice President of Global Regulatory Policy  
Association of Clinical Research Organizations (ACRO)  
Email: [knoonan@acrohealth.org](mailto:knoonan@acrohealth.org)

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### **Data protection statement for 'Public consultation on ACT EU multi-stakeholder platform (ACT EU MSP) participation and priorities for discussion'**

All personal data provided within this questionnaire will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.

This data protection statement provides details on how the Agency, in its capacity as data controller, will process the information that you have given in your questionnaire.

Internally, the Head of Stakeholders and Communication Division is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation. The contact details of the Internal Controller are the following: S-Datacontroller@ema.europa.eu.

### **Collection of data**

Should you answer "yes" to question 4 of this survey, EMA will collect all the personal data provided such as your name, affiliation and email address details. Please do not reveal any other personal data in the free text fields. EMA does not intend to connect your ID with your answers given in the survey.

For the collection of data in this Survey, EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: <https://ec.europa.eu/eusurvey/home/privacystatement>.

The EU Survey external system uses:

Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated. Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.

The local storage contains the IDs of the questions and the draft answers.

IP of every connection is saved for security reasons for every server request. Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage.

Your consent to the processing of your data

When you submit this questionnaire, you consent that EMA will process your personal data provided in the questionnaire as explained in this data protection statement. You may also withdraw your consent later at any time. However, this will not affect the lawfulness of any data processing carried out before your consent is withdrawn.

### **Start of data processing**

EMA will start processing your personal data as soon as this questionnaire is received.

### **Purpose of data processing**

The purpose of the present data processing activity is to collect the views of stakeholders and/or concerned individuals in relation to the particular subject-matter of the survey and to liaise with all respondent who expressed interest in being part of the ACT EU MSP.

### **Location of data storage**

All data is stored within a secure data centre at the EMA premises which is password protected and only available to EMA staff members.

### **Publication of data**

Data collected in this questionnaire will not be published, but aggregated survey results may be shared with third parties.

### **Retention period**

If you complete and send this questionnaire, your personal data will be kept until the results have been completely analysed and utilised. Your personal data will be deleted as soon as the ACT EU MSP is formed (not more than 1 year).

### **Your rights**

You have the right to access and receive a copy of your personal data processed, as well as to request rectification or completion of these data. You may also request erasure of the data or restriction of the processing in accordance with the provisions of Regulation (EU) 2018/1725. You can exercise your rights by sending an e-mail to [S-Datacontroller@ema.europa.eu](mailto:S-Datacontroller@ema.europa.eu).

### **Complaints**

If you have any complaints or concerns about the processing of your personal data, you can contact EMA's Data Protection Officer at [dataprotection@ema.europa.eu](mailto:dataprotection@ema.europa.eu).

You may also lodge a complaint with the European Data Protection Supervisor: [edps@edps.europa.eu](mailto:edps@edps.europa.eu).

**For more details** on how EMA processes personal data, please see the general EMA Privacy Statement: [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://www.ema.europa.eu/en/about-us/legal/privacy-statement)

Please confirm that you have read and understood the data protection statement above and you consent to the processing of your personal data.

### **Contact**

[ACTEU@ema.europa.eu](mailto:ACTEU@ema.europa.eu)